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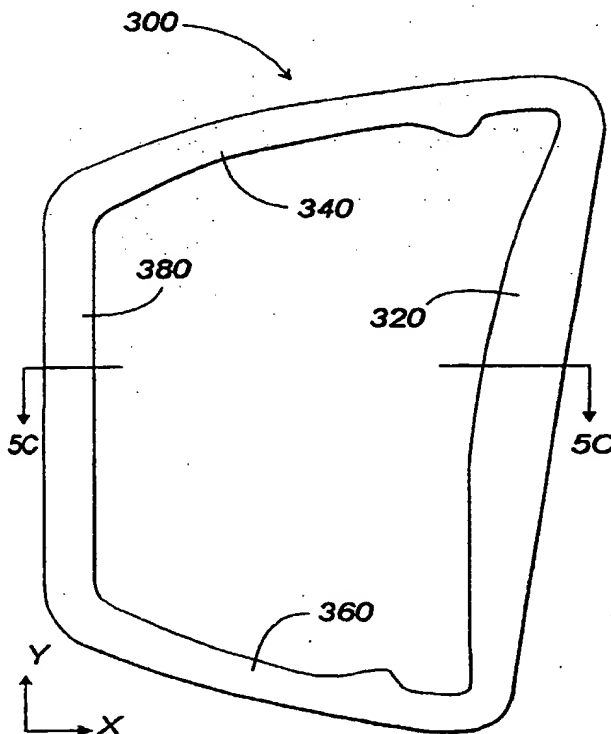
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(57) **Abstract:** A D-ring (100) for connecting a strap (40) to an orthopedic or other brace (10). The D-ring is formed of non-wire material, such as by stamping, casting or forging, thereby lowering manufacturing costs as compared to welded wire D-rings. In a preferred embodiment, the D-ring (100) features a first member (120) that is adapted in shape and varying cross-sectional area to receive the strap (40) and withstand loads imposed by the strap more efficiently. The first member (120) connects via second and third elongated members (140, 160) to a fourth member (180) that is adapted in shape to connect the D-ring (100) and thus the strap to the brace (10). The fourth member (180) may contain additional member thickness to allow more efficient absorption of concentrated stresses imposed by the brace. The size and shape of each member of the D-ring (100) may be optimized by, among other things, varying cross-sectional area and shape. Such D-ring thereby transmits strap/brace loads efficiently while maintaining a flatter, lower profile that conforms more closely to the brace (10), presents less risk of snagging other people or objects during physical activity, and is aesthetically and functionally more pleasing than conventional wire-formed D-ring. D-rings according to the present invention may also be formed using an efficient stamping process. Accordingly, costs are lower, and the result is a strong one piece part.

D-RINGS FOR BRACESBackground of the InventionField of the Invention

The present invention relates to rings or D-rings of the sort employed in braces such as orthopedic braces.

Description of the Related Art

Orthopedic braces are generally used in treatment of injury, in post-surgery applications, as a conservative alternative to reconstructive surgery, or prophylactically in an effort to prevent injury. For example, such braces may be employed after a knee or elbow ligament is injured, or due to disease such as osteoarthritis, after other injuries, or after surgery.

These braces are generally formed of a hinged frame which is adapted to flex with the joint. A number of straps, which are received in a number of D-rings connected to the frame, secure the frame to limbs or body parts. It is critical that the brace properly fit the limb, since an improperly fitted and positioned brace can fail to impose correct restraint or range of motion limits. Consequently, it is important that the straps and rings effectively secure the brace to the wearer's limb throughout the permitted range of motion.

During use, the D-rings may receive static and dynamic loads throughout various ranges of motion. These loads can occur as a result of joint movement or impacts with other players and objects. One such typical conventional D-ring for use in orthopedic braces is depicted in FIGS. 1A-C. Such a D-ring, shown using numeral 2, is generally formed by shaping a length of extruded wire into an open generally D-shaped structure. The structure may be welded closed for additional strength. Thus, a substantial D-shaped D-ring 2 is formed having a weld 4 as shown in FIGS. 1A-C.

Conventional wire-formed D-rings suffer several disadvantages. Deformation of the D-rings which have not been welded closed may affect tightening of the straps and may therefore consequently create difficulty in properly securing the brace to the limb. It is possible to strengthen some conventional wire-formed D-rings by heat-treating them, and also to weld them closed, although with additional expense.

The conventional wire-extruded D-ring is also structurally inefficient because of its uniform cross-sectional area. Because that cross section does not vary, it must accordingly be sufficiently large at all points to withstand maximum load (including tension and bending moment) at any point. As a result, certain portions which are not subject to maximum tension or bending moment may be thicker and wider than actually needed. Whether or not waste of material is an issue, such gratuitous size runs counter to current demand for a more compact, streamlined shape. Instead, it would be preferable for an orthopedic brace to feature D-rings which offer a lower profile, more streamlined appearance, and less potential for snagging other people or other objects during physical activities. It would also be desirable for such D-rings to be formed in three dimensions not only (a) to feature a cross section that varies from one location to the next on the ring according to loads imposed at those locations, but also (b) to conform generally and specifically to shape, size and geometry of adjacent strap and brace elements, and (c) to include structure which is

helpful to reduce or prevent strap bunching. Moreover, it would be desirable for such a three dimensional D-ring to be shaped in one manufacturing process or with minimal manufacturing steps, such as by stamping.

Injection molding has also been used to manufacture plastic three dimensional, one piece D-rings for orthopedic braces. Such D-rings are limited by the materials that are suitable for injection molding and have failed to provide adequate strength, stiffness, and ductility within a suitable low profile.

Summary of the Invention

The present invention provides non wire-formed D-rings for braces which can be formed by processes such as stamping, forging, or casting, thereby lowering manufacturing costs as compared to wire welded D-rings. Such D-rings may accordingly be created to have a shape, dimension and geometry which is optimum for the loads the D-ring will transmit, for a structurally efficient low-profile conformance to the brace and for aesthetic concerns. For instance, a portion of such a D-ring which connects to bracing elements or structure may be dimensioned and configured to feature additional thickness, material and cross section at desired locations in order to accept and accommodate concentrated tension and bending loads imposed by the brace. A portion of the D-ring which connects to strap elements may feature a varying cross section in order to minimize bending loads imposed by the strap elements. Other structure may be added to the D-ring, including to the inner or outer periphery, in order to accommodate or retain in place strap elements or brace elements. Furthermore, the D-ring may be formed in three dimensions in one process or minimal steps, to achieve a structure that is adapted in shape, size and dimension to conform to adjacent brace and strap elements in order to carry loads more efficiently, present a low structural profile, and present an aesthetically pleasing appearance, a necessary functional requirement for orthopedic bracing.

Another embodiment of the present invention provides a brace including a frame, at least one strap, and a D-ring as mentioned above and otherwise in this document.

The present invention also includes methods for manufacturing such D-rings and braces. The methods can include the steps of providing a press with a die, positioning the metal in the press, and stamping the metal to form a coined D-ring (such as one where edges have been rounded).

It is accordingly an object of the present invention to provide D-rings for orthopedic braces which feature greater strength and more efficient structure than conventional D-rings but which are inexpensive and efficient to manufacture.

It is an additional object of the present invention to provide D-rings for braces made by such processes as stamping, casting, or forging.

It is an additional object of the present invention to provide D-rings for braces which may be configured in shape without the need for special welds or post-formation procedures.

It is an additional object of the present invention to provide D-rings for braces having features such as protrusions for guiding brace straps.

It is an additional object of the present invention to provide D-rings for braces with reinforced members and elbows and reduced material at other portions for imparting a more efficient structure and for lowering the profile of the D-ring with respect to the surface of the brace.

Other objects, features and advantages of the present invention will become apparent with respect to the remainder of this document.

Brief Description of the Drawings

Fig. 1A is a top plan view of a conventional welded D-ring.

Fig. 1B is a side elevational view of the D-ring of Fig. 1A.

Fig. 1C is a cross-sectional elevational view taken on line 1C of Fig. 1A.

Fig. 2 is a perspective view of one brace with which D-rings of the present invention may be used.

Fig. 3A is a top plan view of a first embodiment of a D-ring of the present invention.

Fig. 3B is a side elevational view of the first embodiment of the D-ring of the present invention.

Fig. 3C is a cross-sectional elevational view taken on line 3C of Fig. 3A.

Fig. 4A is a top plan view of a second embodiment of a D-ring of the present invention.

Fig. 4B is a side elevational view of the second embodiment of the D-ring of the present invention.

Fig. 4C is a cross-sectional elevational view taken on line 4C of Fig. 4A.

Fig. 5A is a top plan view of a third embodiment of a D-ring of the present invention.

Fig. 5B is a side elevational view of the third embodiment of the D-ring of the present invention.

Fig. 5C is a cross-sectional elevational view taken on line 5C of Fig. 5A.

Fig. 6A is a top plan view of a fourth embodiment of a D-ring of the present invention.

Fig. 6B is a side elevational view of the fourth embodiment of the D-ring of the present invention.

Fig. 6C is a cross-sectional elevational view taken on line 6C of Fig. 6A.

Fig. 7A is a top plan view of a fifth embodiment of a D-ring of the present invention.

Fig. 7B is a side elevational view of the fifth embodiment of the D-ring of the present invention.

Fig. 7C is a cross-sectional elevational view taken on line 7C of Fig. 7A.

Fig. 8A is a top plan view of a sixth embodiment of a D-ring of the present invention.

Fig. 8B is a side elevational view of the sixth embodiment of the D-ring of the present invention.

Fig. 8C is a cross-sectional elevational view taken on line 8C of Fig. 8A.

Fig. 9 is a perspective schematic view of a metal roller for straightening coils of metal which may be used in forming D-rings of the present invention.

Fig. 10 is a perspective view of one type of die press which may be used for stamping D-rings according to the present invention.

Fig. 11 is a graphical depiction of load versus displacement comparing D-rings according to the present invention with each other and a welded D-ring.

Fig. 12 is a graphical depiction of load versus displacement comparing D-rings according to the present invention with each other and welded D-rings.

Fig. 13 is a graphical depiction of load versus displacement comparing D-rings according to the present invention with each other and welded D-rings.

Fig. 14 is a front elevational view of a D-ring mounted on two tester grips.

Fig. 15 is a cross sectional view of a D-ring according to a preferred embodiment of the present invention conforming to a brace.

Detailed Description of the Preferred Embodiment

As used herein, "D-ring" means a structure for receiving straps and other retention devices and transmitting loads in braces such as orthopedic braces, and includes circular, oval, open, triangular, rectangular, trapezoidal and D-shaped structures.

"Member" means a length of material forming part of a D-ring.

"Elbow" means an angle or curve in the D-ring between two members.

"Member length" means longitudinal direction of a member at a given point.

"XY plane" means a plane defined by the X- and Y-axes as shown for example in Figs. 3-8.

"Member width" means dimensionality of a cross section of a member at any particular point on the member, substantially perpendicular to the member length, as shown for example by numeral 126 in Fig. 3C.

"Greatest width" means the greatest member width for a particular member.

"Member thickness" means dimensionality of a cross section of a member substantially perpendicular to member width and member length at any particular point on the member as shown for example by numeral 122 on Fig. 3C.

Accordingly, Figs. 1A-1C show one particular conventional wire-formed orthopedic brace D-ring 2 which features four members spanning four elbows, two of the members also each featuring an arch to cause the D-ring to extend out of a substantially single plane. A weld 4 is located in the member 9 which connects to a brace. The other member 8, which is adapted to receive and connect to a strap of the brace, is longer than, or has a greater member length, than member 9. Fig. 1C shows that the cross sections of members 8 and 9 are circular, as would be expected in an extruded wire structure. The D-ring has been bent to lie partially out of the XY plane, in a forming process. The uniform cross section of the members of D-ring 2 limit potential for additional thickness or width which could add strength in desired locations. Additionally, the sharp wire bending and forming necessary to create the elbows of D-ring 2 can compromise the strength of the wire material at those locations.

Fig. 2 depicts one sort of brace 10 which may be used with D-ring 2 or D-rings of the present invention, and which is adapted to fit a knee and leg. D-rings of the present invention may be used with any desired bracing. Brace 10 can include a frame 20, straps 40, mounts 50, pads 60, and D-rings 100. Pads 60 may be positioned proximate to the joint to which brace 10 is applied. D-rings 100 may be connected to frame 20 using mounts 50, which receive the D-rings 100. Other structures may just as easily be used to connect D-rings 100 to the brace 10 as desired. For

instance, a D-ring 100 may be connected in a manner that allows it to pivot in one or more planes, or it may be connected in a manner that is more restrictive as to relative motion between the D-ring 100 and the brace 10. When a mount such as mount 50 is employed, it may accommodate one or more D-rings 100. When two D-rings 100 are connected to the brace 10 using a single mount 50, they may be positioned in a butterfly configuration 80. Each D-ring 100 forms an aperture 104. Straps 40 which connect to the D-rings preferably partially circumscribe the leg of a wearer to retain the brace 10 in position on the body member throughout a desired range of motion. Straps 40 may be elastic, partially elastic or non-elastic. As shown in Fig. 2, one end of a strap 40 that features a hook and loop fastener material extends through D-ring 100 and fastens back onto itself using hook and loop fastener material on another portion of the strap 40. Although a hook and loop fastener material has been described for securing strap 40, other suitable means may be used such as fasteners, buckles, catches and clasps.

A D-ring 100 according to the present invention, which may be used with orthopedic bracing of the sort shown in Fig. 2, is shown in greater detail in Figs. 3A-C. Directional x-, y- and z-axes are also shown; the XY plane can be considered parallel to a table top on which D-ring 100 is placed, and the Z axis is the depth of thickness plane that is perpendicular to the XY plane and extends vertically from the table top. The D-ring 100 can include a first member 120, a second member 140, a third member 160, and a fourth member 180. Preferably, first member 120 and second member 140 are formed integrally with a first elbow 130, first member 120 and third member 160 are formed integrally with a second elbow 150, second member 140 and fourth member 180 are formed integrally with a third elbow 170, and third member 160 and fourth member 180 are formed integrally with a fourth elbow 190. These elbows 130, 150, 170 and 190 give rounding to the appearance of the D-ring 100, while members 120, 140, 160 and 180, with their interconnecting elbows, form a unitary piece that creates the aperture 104 for receiving a strap 40. D-ring 100 may assume any desired shape. As an example, D-ring embodiments may take a triangular form with first, second and third members. The second and third members may form a single elbow that is coupled to the brace 10. As a further example, the D-ring could be substantially U-shaped with elbows 170 and 190 coupling directly to brace 10; in such a structure, member 180 is absent. Similarly, the two elbows 170 and 190 could be omitted. Furthermore, D-rings 100 may be constructed from metal, plastics, or composite materials.

Member 120 in the particular D-ring 100 shown in Fig. 3 is skewed longitudinally in the XY plane in order to impart direction to the strap 40 it receives so that the strap 40 is oriented more effectively to fit the wearer's limb. Member 120 may be oriented at any desired angle with respect to member 180, however, including parallel. Members 140 and 160 are shown slightly curved, although they may be formed straight or as otherwise desired. They are shown with tapering member width along their length, although they could be of any desired member width and member thickness. Preferably, for at least some of the locations on the D-ring, member width corresponds to the stress that those locations experience when the D-ring is subject to loads in use. Member thickness can also be similarly varied if desired.

Elbows 170 and 190 can be formed at more oblique angles than elbows 130 and 150, which are adjacent the strap. (A different radius of curvature may also be used.) Additionally, those elbows, and member 180 which is also

adjacent to the mount 50 or a brace, can be formed to feature additional cross sectional area for additional strength. As shown in Fig. 3A, member 180 and elbows 170 and 190 can feature additional member width. This additional member width causes elbows 170 and 190 to contain more cross-sectional area at 172 and 192 respectively, and thus more material for additional strength at a given location, than elbows 130 and 150.

5 Figure 3A also shows member 120 having a member width that increases to maximum at approximately the middle of its member length. Figure 3C shows the member width at approximately that middle location. This tapered width may be formed to correspond at least generally to the loading imposed on member 120 by the strap. Given that the strap imposes load on member 120 across the width of the strap and corresponding length of member 120, member 120 acts in some senses as a beam which bears greatest load at its approximate midpoint, as shown in
10 Figure 3A. The member thickness and member width of the member 120 may just as easily be tailored to accommodate any particular loading that member 120 is expected to bear.

Members 120 and 180 can be formed with rounded perimeters to prevent fraying of strap 40 and to permit the rotation of member 180 within mount 50. These rounded perimeters may be formed by a coining process, which will also tend to increase the strength of the D-ring 100.

15 Coining is a metal forming process whereby metal is shaped, rather than pierced, to a desired configuration. Generally, coining is used to round sharp edges, and because of this shaping process, strength improvements occur due to strain hardening. Coining can be performed as part of the metal stamping process in a progressive metal stamping die or as a separate manufacturing process.

Members 140 and 160 can feature respective irregularities such as protrusions 142 and 162 for retaining a
20 strap 40 in place relative to the D-ring 100, in order to promote ease of use and to prevent the strap from inadvertent movement relative to the D-ring 100 during use or when it is being applied to the joint and limb. These protrusions may be of any desired size, configuration, geometry and location to retain a particular strap as desired relative to the D-ring.

D-rings according to the present invention, as shown in Fig. 3, may feature smaller member thickness than wire-formed D-rings or plastic injection molded D-rings, and thus present a lower profile to conform better to the brace.
25 This lower profile presents less interference to adjacent objects, the brace wearers themselves, or other people when the person wearing the brace is engaged in physical activity. Member thickness 120, 140, 160 and 180, and elbows 130, 150, 170 and 190 may be reduced at any particular location, if desired, in favor of increased member width at those locations in order to impart desired strength characteristics. Fig. 3C shows the additional member width imparted to member 120 in order to accommodate loading by the strap.

30 A portion or portions of members 140 and 160 can be arched out of the XY plane thus to position those portions out of that plane as desired with respect to member 180 in order to allow the D-ring 100 to conform better to the particular brace and the strap with which it is used. In such a case, as shown in Figs. 3B and 3C, for example, member 120 is out of the XY plane that contains member 180. Any portion of the D-ring 100 may be oriented in any desired direction for optimum load bearing, conformance, load directing, and other functional and/or aesthetic ends.

This orientation may be imparted in the same stamping or other manufacturing process as that in which the D-ring is otherwise formed, thus simplifying manufacturing efforts.

A few other examples of the many D-ring configurations according to the present invention are shown in Figs. 4A-C through 8A-C and discussed below. These D-rings may be formed from materials and processes the same as or similar to the materials and processes of D-ring 100 discussed above.

Referring to Figs. 4A-C, a D-ring 200 can have a first member 220, a second member 240, a third member 260, and a fourth member 280. D-ring 200 is identical to D-ring 100, with the exception that members 240 and 260 curve upwardly in the z-direction with respect to member 280. Thus, member 220 is positioned in an upward orientation with respect to member 280.

Referring to Figs. 5A-C, a D-ring 300 can include a first member 320, a second member 340, a third member 360, and a fourth member 380. D-ring 300 is identical to D-rings 100 and 200, with the exception that members 340 and 360 are substantially straight, so that no portions of members 340 or 360 are arched out of the XY plane; member 320 is thus located in the same XY plane as member 380.

Referring to Figs. 6A-C, a D-ring 400 includes a first member 420, a second member 440, a third member 460 and a fourth member 480. These members 420, 440, 460 and 480 form a substantially trapezoidal structure. D-ring 400 is similar to the earlier described D-rings, except that member 420 is substantially parallel with member 480, thereby creating a substantially trapezoidal structure. Members 440 and 460 in this particular embodiment of the invention are arched out of the XY plane at approximately 41.5 degrees.

Referring to Figs. 7A-C, a D-ring 500 can include members 520, 540, 560 and 580, forming a substantially trapezoidal structure. D-ring 500 is substantially the same as D-ring 400 except that members 540 and 560 are not arched out of the XY plane, thereby positioning member 520 in about the same XY plane as members 580, 540 and 560.

Referring to Figs. 8A-C, a D-ring 600 can include member 620, 640, 660 and 680 forming a substantially rectangular structure. Members 640 and 660 are not arched out of the XY plane, thereby positioning members 620, 640, 660 and 680 in substantially the same XY plane.

The above-described D-rings of the present invention are formed as enclosed structures by such processes as stamping, casting or forging, which reduces manufacturing costs as compared to prior art processes that extrude, bend, and weld a wire material. One process for forming D-rings of the present invention is stamping. Equipment used to stamp the D-ring is shown schematically in Figs. 9-10. Almost any type of metal can be used to form the D-rings. Potential metals can include, among a wide array of choices, 304 stainless steel (SS) 1/4 hard, annealed 304 SS, 4130 Steel 40 Rockwell C, 4130 Steel 45 Rockwell C, 6061-T6 aluminum, 5052-H32 aluminum, and non-heat-treated 4130 steel. This material can be supplied in the form of sheets or coiled metal. According to a preferred embodiment, D-rings according to the present invention are formed using 4130 Steel, non heat-treated, which is powder coated after stamping with O'Brien Black Cat Polyurethane UFB-502-S3. After stamping and before powder coating, the D-rings are preferably deburred in a conventional manner. If the material is in sheet form, it can be fed directly into a

conventional press 920 as shown in Fig. 10 equipped with dies that create the shape and configuration of the D-ring. Alternatively, if the material is coiled, it may be flattened in a conventional metal flattener or roller 910 as shown in Fig. 9. Metal flattener 910 can be any suitable machine that provides flattened metal sheets or strips from coiled metal. After flattening, the material is then fed, either automatically or by hand, into the press 920. The press 920 includes a die 930.

The metal is first stamped with a sharp die to create the D-ring in three dimensions. If desired, this die may also coin the D-ring during this same stamping process to produce rounded edges. Preferably, these rounded features are present on at least the first member and fourth member of the D-rings as described above, in order to provide more functional and wear resistant connection to the brace and the strap. Furthermore, portions of the D-ring may also be arched out of the XY plane as shown, for example, in Figs. 3, 4 and 6, during the stamping process.

Referring to Fig. 15, D-ring 100 receiving strap 40 is attached to frame 20 of brace 10 by mount 50. As depicted by Fig. 15, the arched configuration of D-ring 100 adapts its shape to the configuration of brace 10 by "wrapping" around the frame's edge. This close conformity around the edge of frame 20 provides a proximal fit between D-ring 100 and brace 10, and prevents D-ring 100 from snagging other objects.

Experimental Testing

Comparative testing was performed to compare a conventional welded D-ring with stamped D-rings of the present invention. The tests included a corrosion test and strength testing.

Corrosion Testing

The specimens for a corrosion test included: (1) a conventional welded D-ring formed of 302 SS 1/2 hard wire with black oxide coating and obtained from DonJoy, 2985 Scott Street, Vista, CA 92083 and (2) several D-rings according to the present invention stamped from materials as shown in Table 1 below. The stamped D-ring specimens were of the same shape and size, corresponding generally to the shape shown in Fig. 7. Specimen 1, the wire-formed D-ring was generally of the same shape (not including member width and member thickness) as the stamped D-ring specimens. None of the specimens were coined. But the 40 Rockwell C specimens were heat-treated and the 304 and above-described 302 stainless steel specimens were strain hardened. In addition, materials from other parts of an orthopedic brace, namely an aluminum gear and a hinge plate, were tested for corrosion resistance as well. Table 1 lists the specimens:

TABLE 1	
Specimen Number	Material
1	Welded D-ring
2	Stamped 304 SS 1/4 hard bare
3	Stamped 304 SS 1/4 hard powder-coated
4	Stamped 4130 40 Rockwell C steel bare

5	Stamped 4130 40 Rockwell C steel powder-coated
6	Stamped 6061-T6 aluminum gear
7	Stamped 304 SS ½ hard hinge plate

Powder coated D-rings featured an electrostatically applied plastic coating of polyurethane.

The test procedures consisted of scribing specimens to a depth of about five-thousandths of an inch (0.125 mm) with the edge of a standard metal file. The specimens were then salt-sprayed pursuant to ASTM B117-95 standard (which is incorporated by this reference) for 96 hours. The condition of each sample was then noted. The results of this test are shown in Table 2.

TABLE 2	
Specimen 1	Mild surface rust with no visible rust in the scribe
Specimen 2	Significant surface rust
Specimen 3	No surface rust in coated regions and mild rust in the scribe
Specimen 4	Heavily corroded with rust and scaling
Specimen 5	No surface rust in coating regions and mild rust in scribe
Specimen 6	No visible rust
Specimen 7	No visible rust

Specimens 6 and 7, aluminum gear and stainless hinge plate exhibited less corrosion than the conventional welded D-ring (Specimen 1). It may be concluded that powder coated stamped D-rings are preferable to non powder coated stamped D-rings and are generally comparable in performance to the wire-formed D-ring for corrosion resistance to saline solutions (although powder coating is not a necessary feature of D-rings according to the present invention).

Strength Tests

Example 1

Strength testing was performed to assess deformation characteristics of various D-rings as a function of load imposed. The testing apparatus employed was an MTS tester obtained from MTS Systems Corporation, 1400 Technology Drive, Eden Prairie, Minnesota 55344-2290. The MTS tester was calibrated using procedures written in accordance with standard calibration practices such as ASTM E4, ASTM E83, or MIL-STD-45662A (all of which are incorporated herein by this reference). As shown schematically in Fig. 14, the tester included a movable grip 950 and a stationary grip 952. Each grip 950 and 952 featured two 3/16 inch (4.75 mm) diameter pins -- pins 960 and 962 and pins 970 and 972 respectively. Pins 960 and 970 were separated from pins 962 and 972 by about 0.5 inches (12.5 mm).

Testing was initially performed with four stamped prototype D-rings, of a non-optimized shape, and a welded wire-form D-ring. Yield strengths for these five specimens were observed and recorded. Yield strength of a material is the maximum allowable stress that the material will withstand before plastic (permanent) deformation occurs.

The tested D-rings were of the same shape and size (member width and member thickness of the stamped specimens differing from that of the wire-formed D-rings). None of the specimens were coined, but the Rockwell C specimens were heat-treated, one 304 stainless steel specimen was annealed, while the rest of the 304 stainless steel specimens were strain hardened to either $\frac{1}{4}$ or $\frac{1}{2}$. The five specimens were: unsprayed specimens 1, 2, and 5 having the same material, structure and finish as listed in Table 1 above; and two other specimens, specimens 8 and 9. Specimens 8 and 9 were D-rings stamped from, respectively, annealed 304 stainless steel and 4130 steel 35 Rockwell C.

To begin the procedure, a stamped D-ring or welded D-ring was mounted on the pins 960, 962, 970, and 974. The upper grip was displaced in a controlled manner and loads and deformation (displacement of the pins relative to each other) were noted. The results of this test are plotted as load versus displacement as shown in Fig. 11. Failure was considered to be when the D-rings reached their elastic limits (yield strength). This is the point at which the slope of the curve becomes non-linear.

Specimens 1, 2, 5, 8, and 9 yielded at approximately 170, 170, 190, 75 and 160 pounds (75 kg, 75 kg, 86 kg, 34 kg and 73 kg), respectively, suggesting that all of the stamped D-rings had yield strengths comparable to the welded wire-form D-ring except Specimen 8, which yielded at a considerably lower load.

Example 2

Additional stamped D-rings were constructed of a further optimized geometry, substantially equivalent to the D-ring shown in Fig. 7, and additional tests were performed using specimens as shown in Table 3 in order to determine overall strength, as well as the relative effect of heat treating:

TABLE 3	
Specimen Number	Material
10	Welded D-ring obtained from DonJoy as described above in the corrosion testing
11	Heat-treated stamped D-ring made from 4130 steel Rockwell 40 C
12	Non-heat-treated stamped D-ring made from 4130 steel

Two D-rings of specimen 10, two D-rings of specimen 11, and one D-ring of specimen 12 were tested in accordance with the procedure described for Example 1. None of the stamped D-rings were coined. The results in the form of load displacement curves are shown in Figure 12.

Figure 12 shows that heat-treated D-ring specimens 11 withstood loads up to approximately 230 pounds (105 kg) without yielding (where the curves generally assume non-linearity) whereas the welded wire-formed D-ring specimens 10 yielded at much lower loads. The non-heat-treated D-ring of specimen 12 yielded at approximately 150

pounds (68.2 kg). As a general matter, it can be concluded that the stamped D-rings heat-treated or not, were able to withstand more load than the welded wire formed D-rings.

Example 3

5 Final testing was conducted on 4130 40 Rockwell C heat-treated and non-heat-treated D-rings made according to the present invention, which were substantially equivalent to the D-ring shown in Fig. 7; versus welded D-rings obtained from DonJoy of Vista CA. All of these stamped D-rings were coined. These procedures were conducted as described above for Example 1. Five heat-treated stamped D-rings, four non-heat-treated stamped D-rings, and two (non-heat-treated) welded D-rings were tested. The results in the form of load displacement curves are depicted in Fig. 13.

10 Fig. 13 shows that heat treating improves the performance of the 4130 40 Rockwell C stamped D-rings, relative to the non-heat-treated D-rings. It also shows that even the non-heat-treated D-rings feature superior load displacement response to the conventional wire formed D-rings.

The foregoing is provided for purposes of explanation and disclosure of preferred embodiments of the present invention. Modifications, additions and/or deletions may be made to the structures where their components shown and described in this document without departing from the scope or spirit of the invention.

15

WHAT IS CLAIMED IS:

1. A D-ring for use in connecting a strap to an orthopedic brace, the D-ring comprising:

(a) a first member for connection to the strap, the first member featuring a cross section having substantially constant thickness and a width which tapers substantially continuously from narrow at the ends to maximum at approximately the midpoint of the first member;

(b) second and third members connected to the first member by a pair of rounded elbows;

(c) a fourth member for connection to the brace, the fourth member including additional thickness for imparting additional strength to the fourth member in order to withstand loads imposed on the D-ring by the brace;

(d) a pair of rounded elbows connecting the second and third members to the fourth member, the elbows each including additional thickness for imparting additional strength;

(e) wherein the D-ring is formed by stamping.

2. A D-ring according to Claim 1 in which edges of the D-ring are coined.

3. A D-ring according to Claim 1 in which the second and third members each include at least one protuberance that is adapted to restrain positioning of the strap relative to D-ring.

4. A D-ring according to Claim 1, in which the fourth member and the first member are not substantially parallel.

5. A D-ring according to Claim 1, in which the first member is substantially parallel to the fourth member.

6. A D-ring according to Claim 1, in which the first, second, third and fourth members are positioned in substantially the same plane.

7. A D-ring according to Claim 1, in which the first, second, third and fourth members are not positioned in substantially the same plane, the D-ring thereby configured in shape to conform its corresponding brace.

8. A D-ring according to Claim 1, in which the second and third members feature varying cross-sections along their length.

9. A D-ring according to Claim 1, adapted to connect to the brace using a mount connected to the brace.

10. A D-ring according to Claim 1, in which the D-ring is heat-treated.

11. A D-ring according to Claim 1, in which the D-ring is powder coated.

12. A brace, comprising:

(a) at least one frame adapted to fit a body part and connected to at least one hinge;

(b) at least one strap for retaining the frame to the body part; and

(c) at least one D-ring as recited in Claim 1 for securing the strap.

13. A brace according to Claim 12, wherein edges of the D-ring are coined.

14. A brace according to Claim 12, in which the fourth member and the elbows connecting the fourth member and the second and the third members feature additional member width adapted to impart additional strength to the fourth member and the elbows.

5 15. A brace according to Claim 12, further comprising at least one irregularity formed on the surface of the D-ring for retaining the strap in a predetermined position relative to the D-ring.

16. A brace according to Claim 12, in which the D-ring is powder coated.

17. A brace according to Claim 12, in which the first member is substantially parallel to the fourth member.

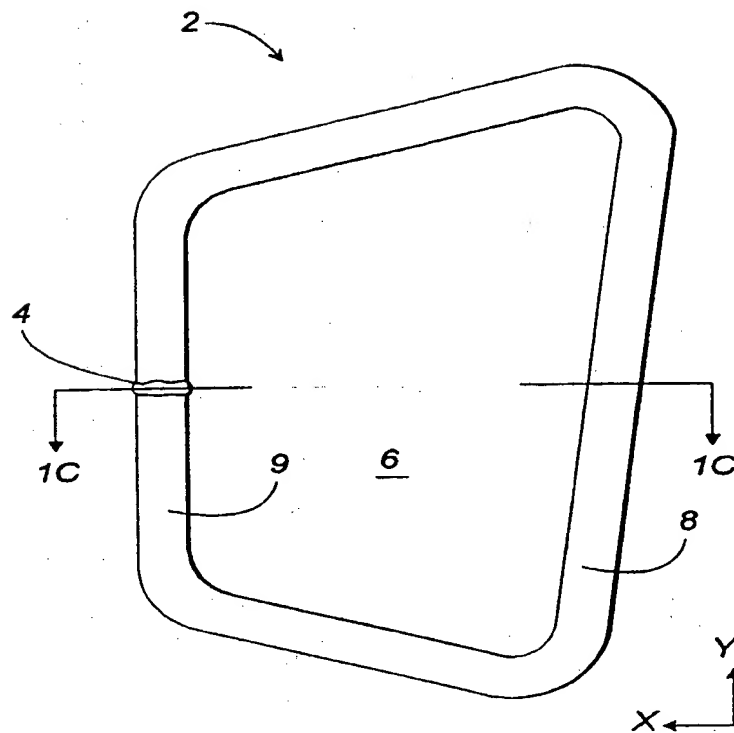
10 18. A brace according to Claim 12, in which the first member is not substantially parallel to the fourth member.

19. A brace according to Claim 12, in which the first, second, third and fourth member are positioned in substantially the same plane.

20. A brace according to Claim 12, in which the first, second, third and fourth members are not positioned in substantially the same plane, the D-ring thereby configured in three dimensions.

15 21. A brace according to Claim 12, in which the D-ring is connected to the brace using a mount.

22. A brace according to Claim 12, in which the D-ring is connected to the frame.



(PRIOR ART)

FIG. 1A

(PRIOR ART)

FIG. 1B

(PRIOR ART)

FIG. 1C

A

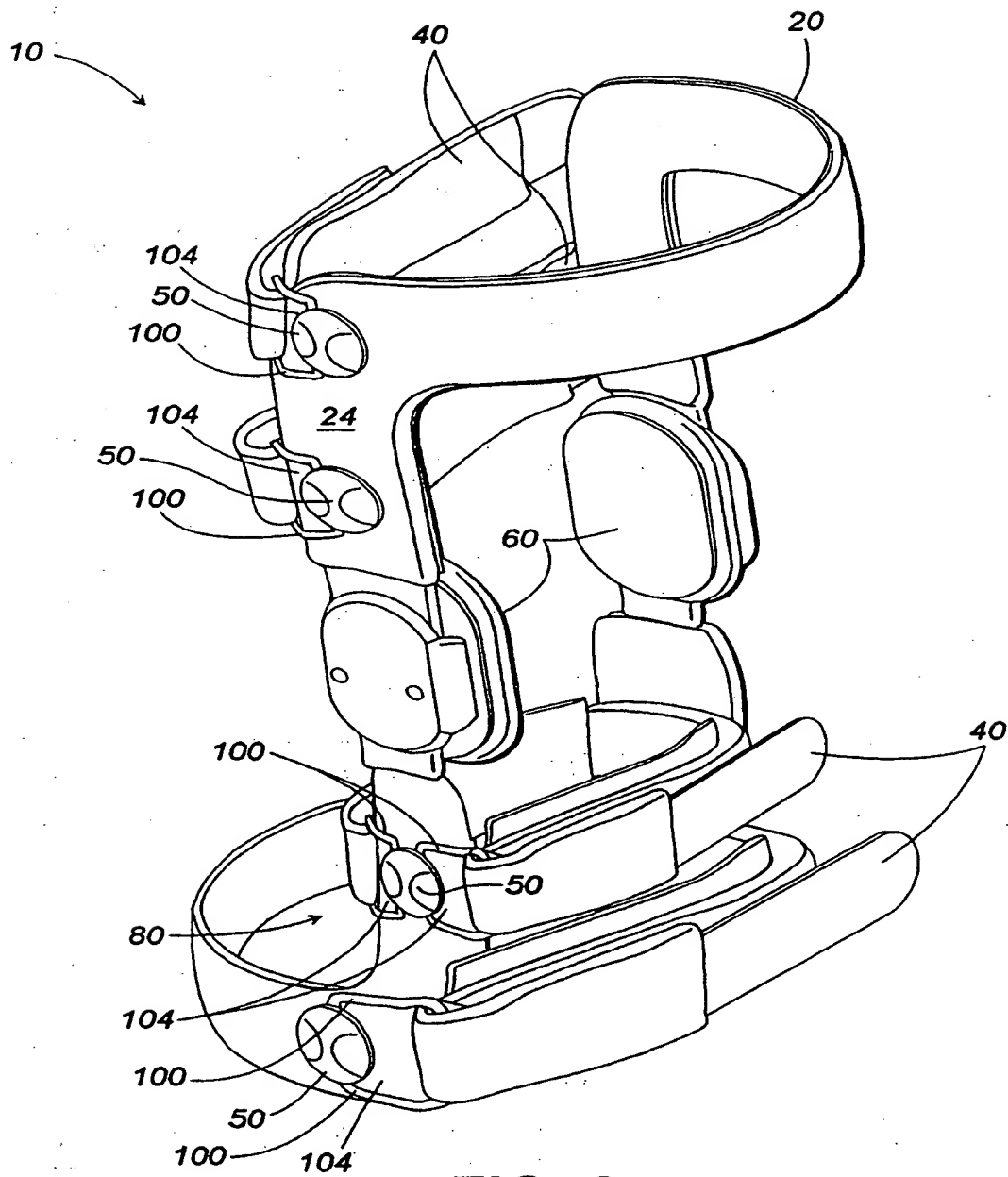


FIG. 2

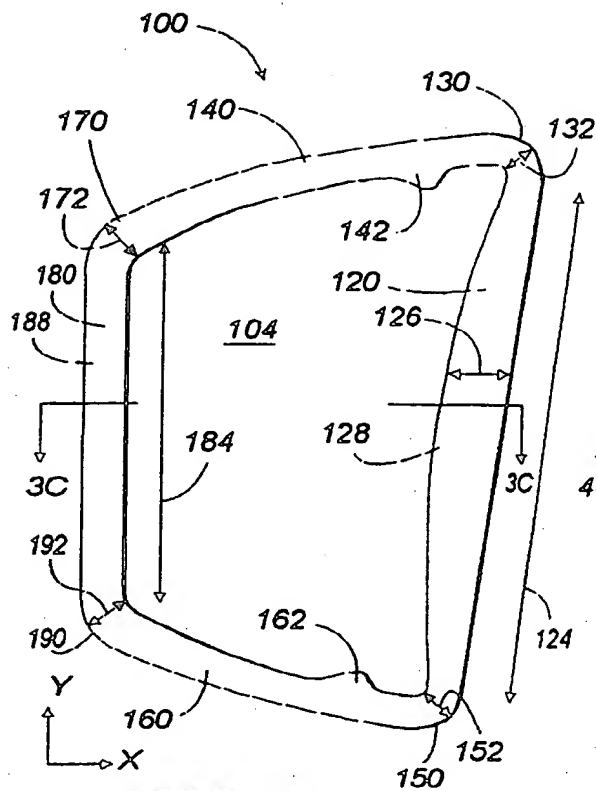


FIG. 3A

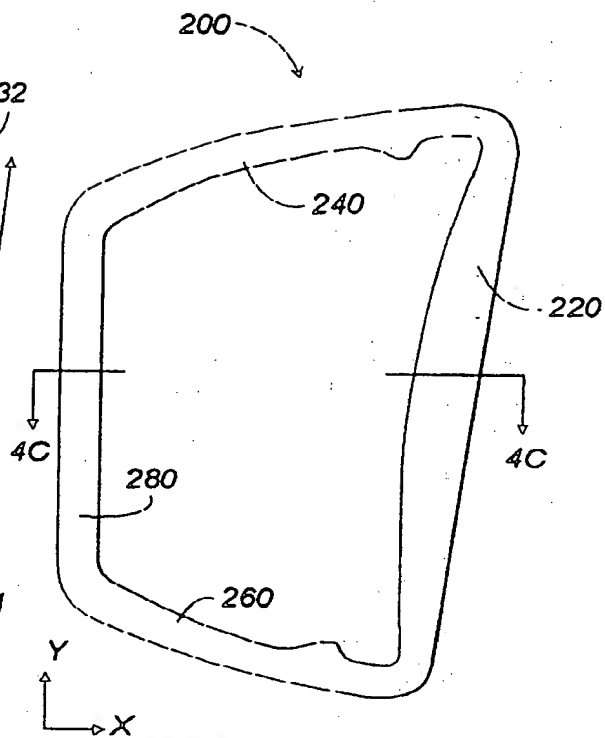


FIG. 4A



FIG. 3B

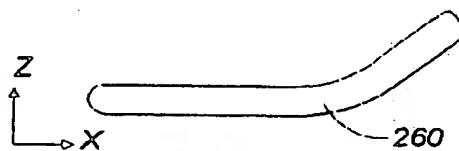


FIG. 4B

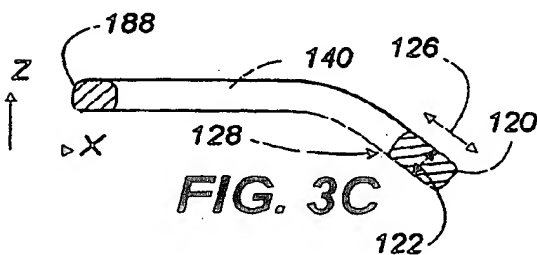


FIG. 3C

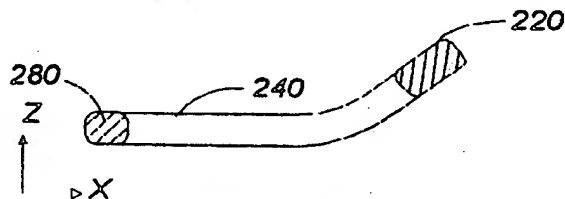
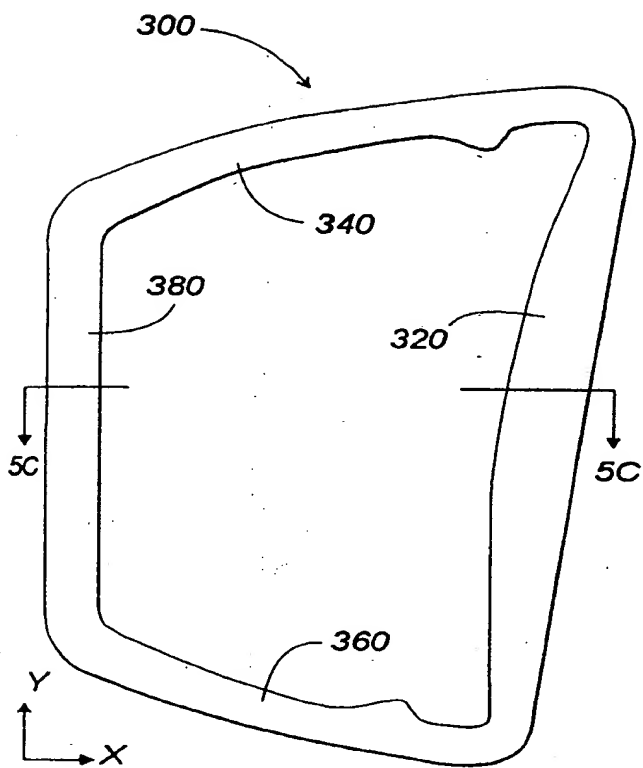
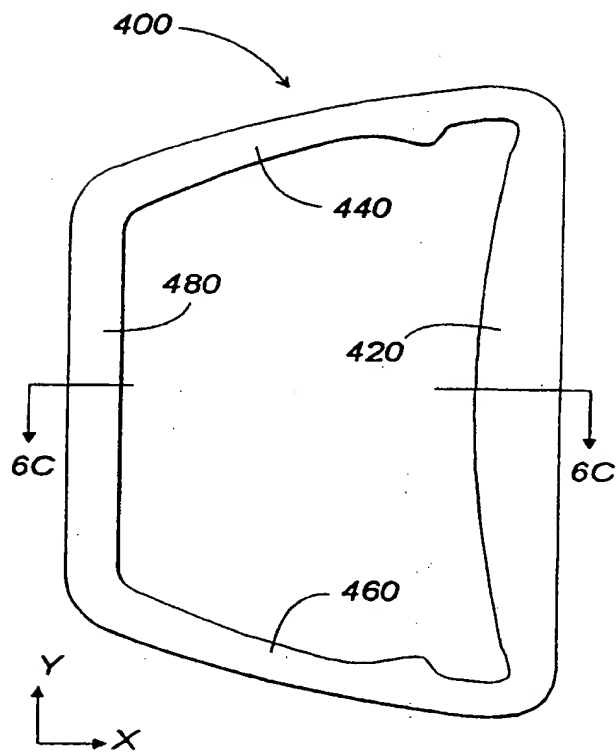
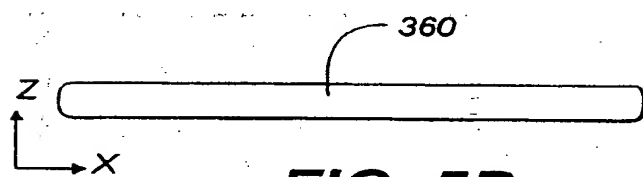
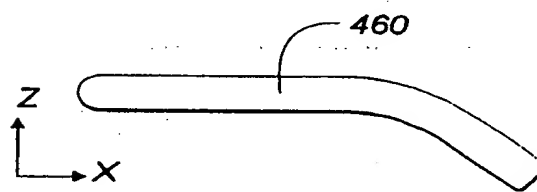
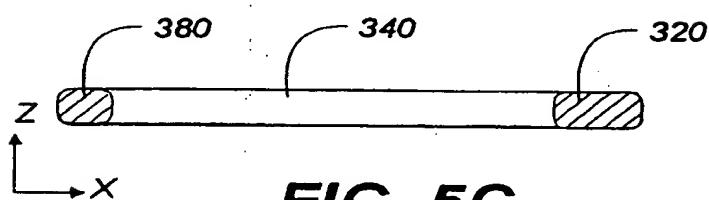
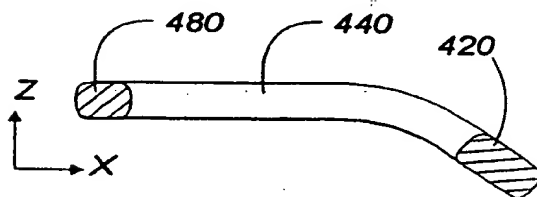
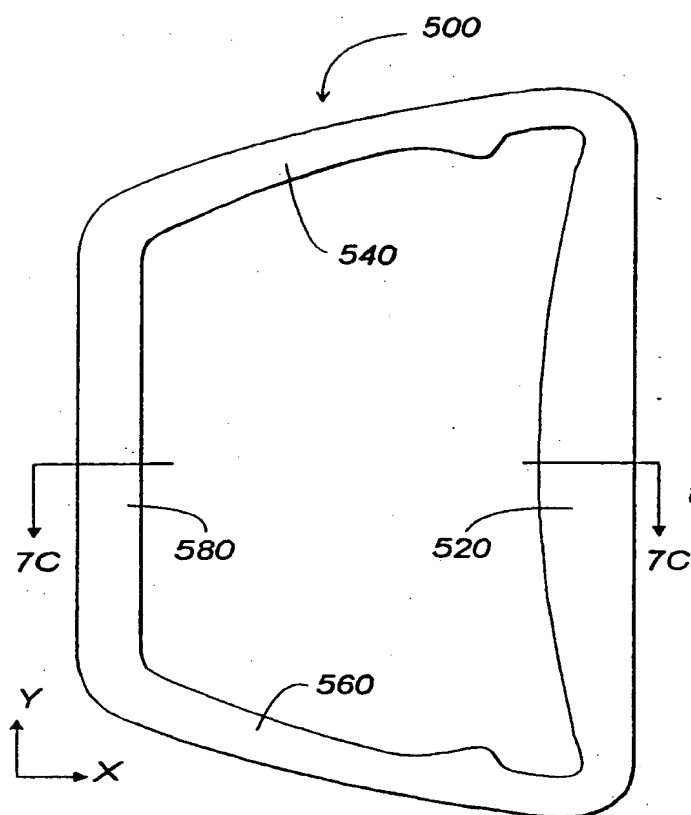
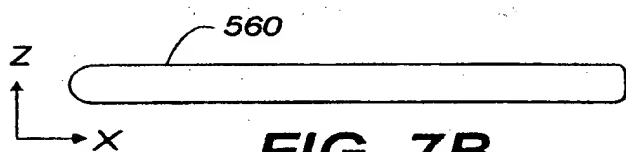
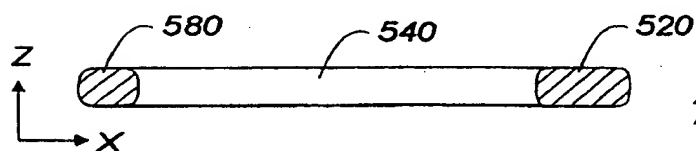
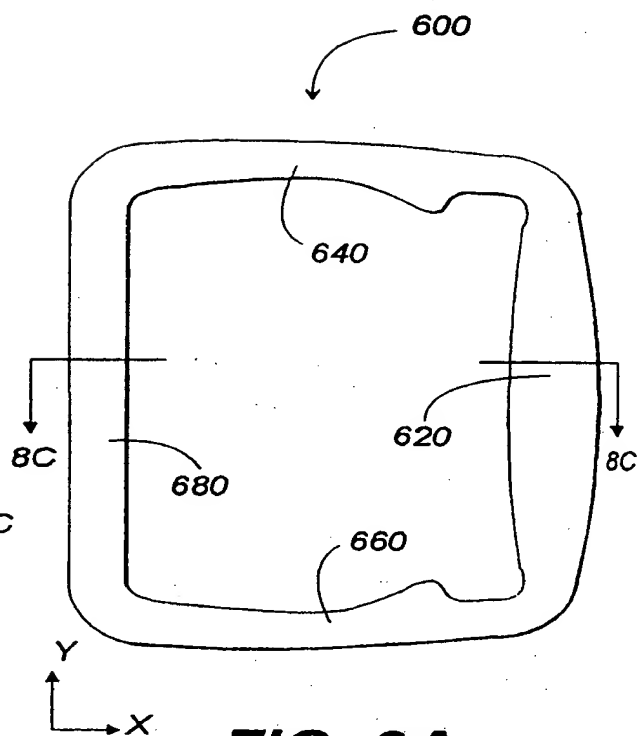
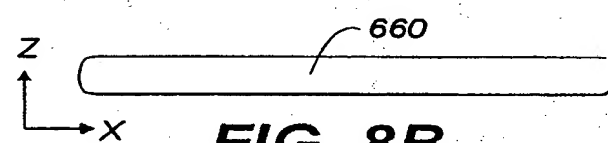
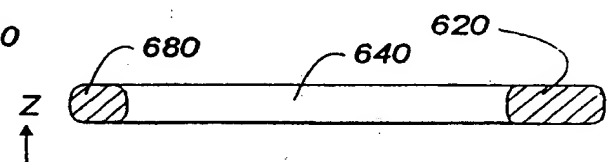


FIG. 4C

**FIG. 5A****FIG. 6A****FIG. 5B****FIG. 6B****FIG. 5C****FIG. 6C**

**FIG. 7A****FIG. 7B****FIG. 7C****FIG. 8A****FIG. 8B****FIG. 8C**

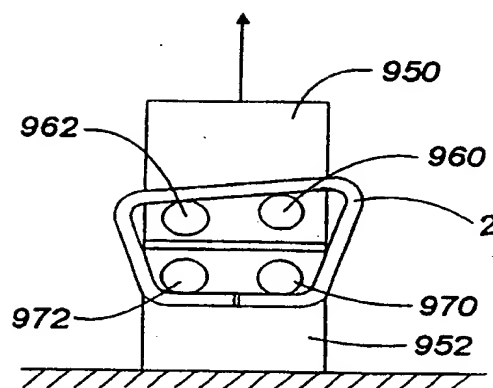
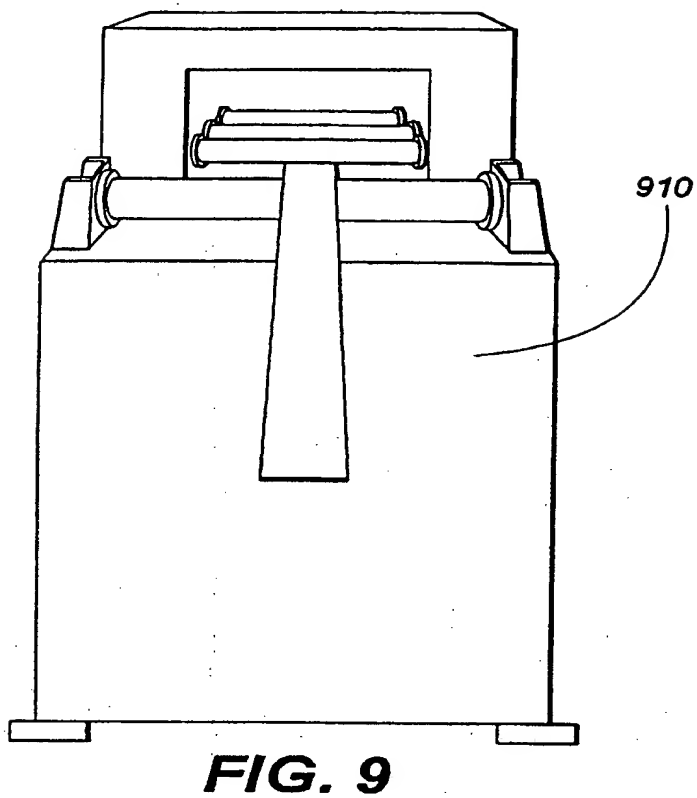


FIG. 14

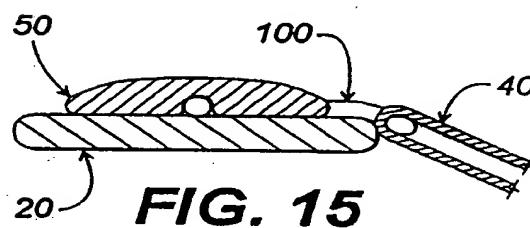


FIG. 15

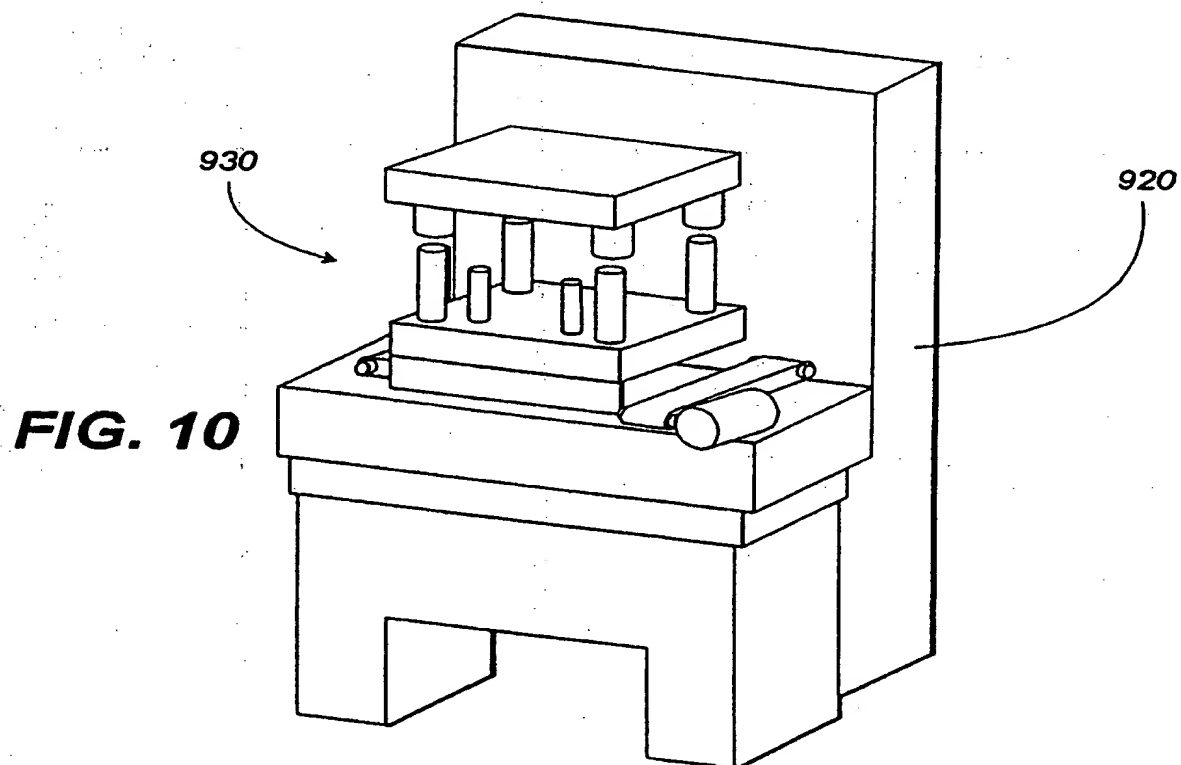


Figure 11

Strength Test

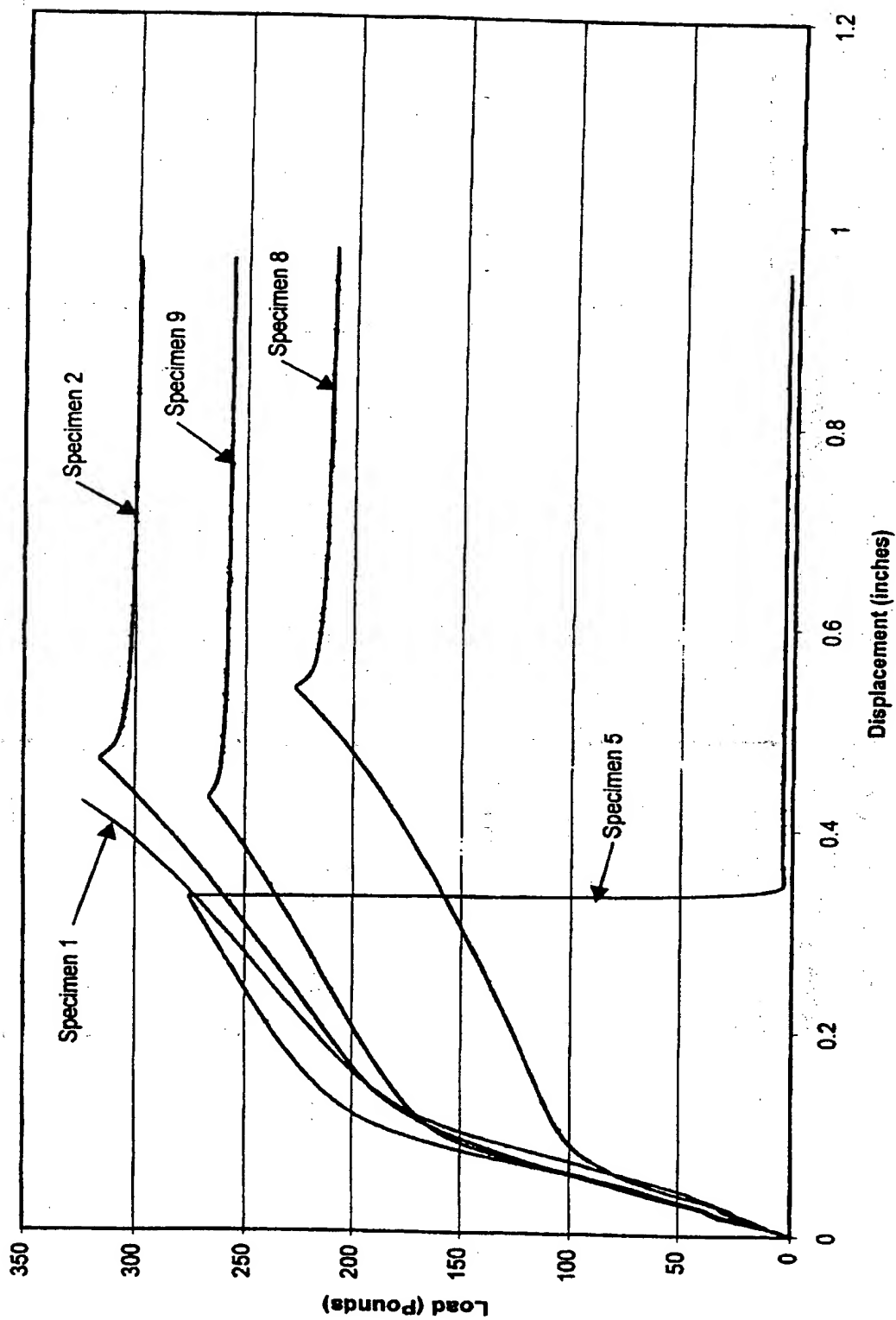


Figure 12

Strength Test

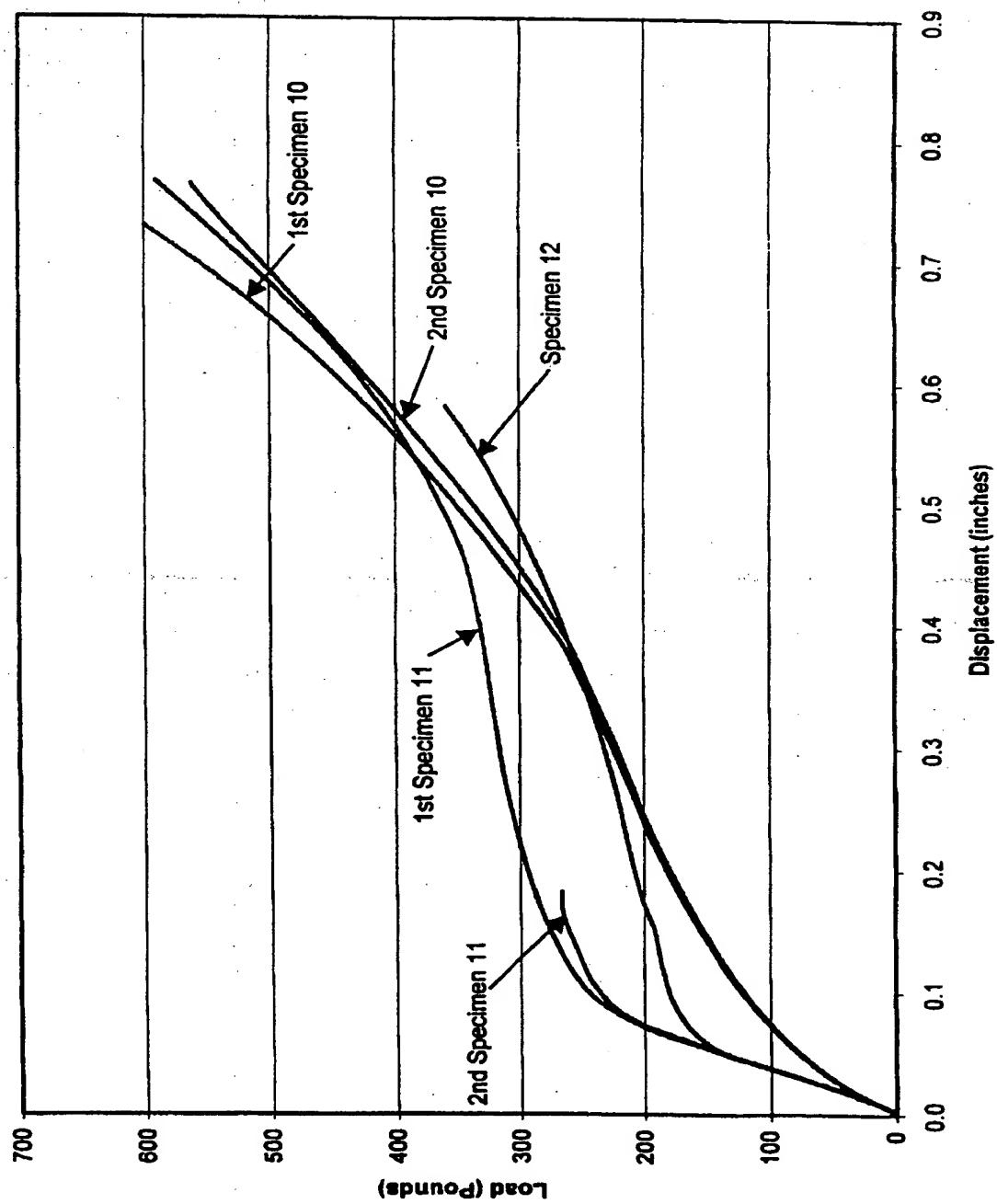
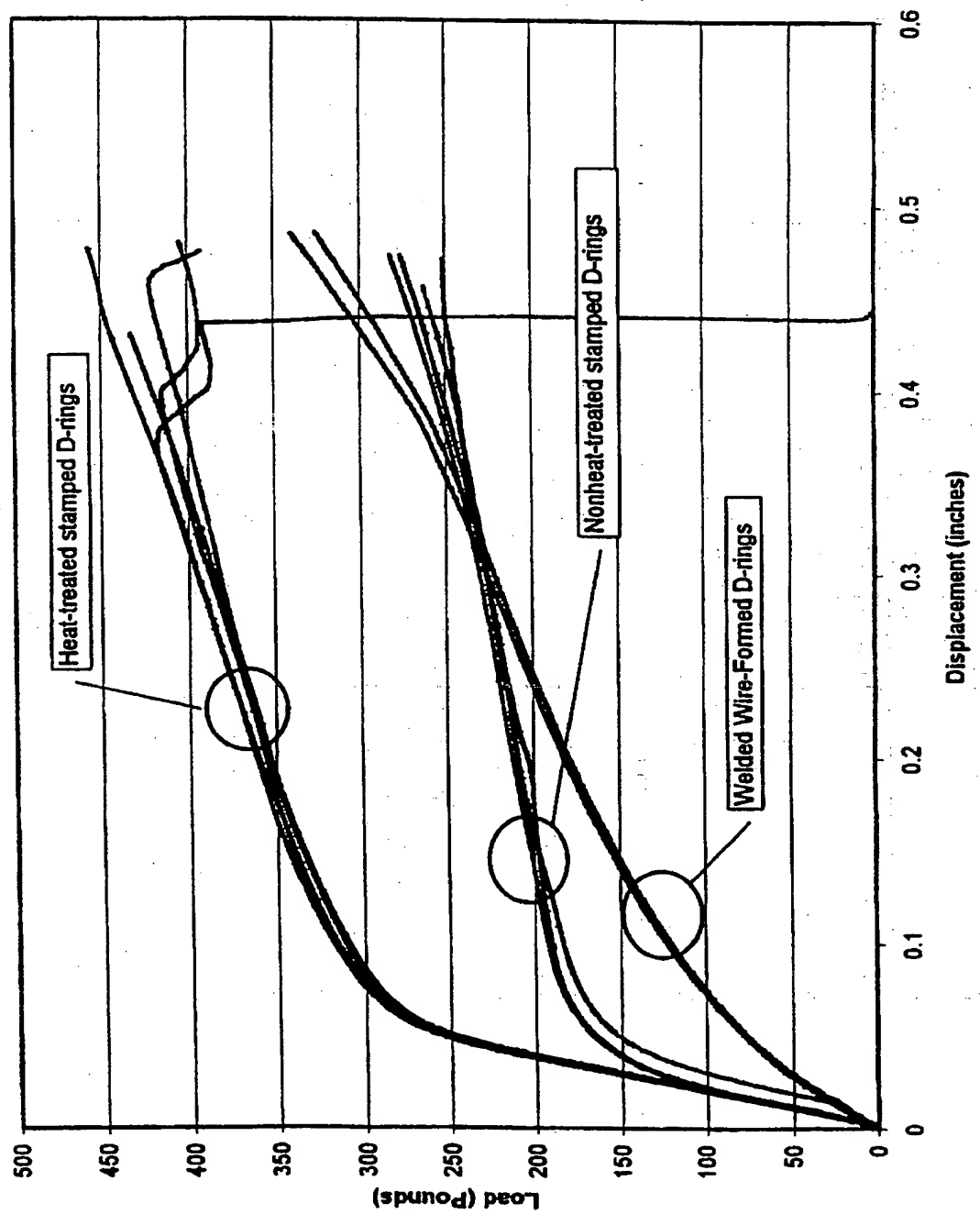


Figure 13

Strength Test



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/14779

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F5/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F B21F B21D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 633 867 A (KAUSEK JAMES H ET AL) 6 January 1987 (1987-01-06) abstract	1, 12
A	EP 0 873 437 A (BRAECKER AG) 28 October 1998 (1998-10-28)	
A	US 4 869 267 A (GRIM TRACY E ET AL) 26 September 1989 (1989-09-26)	
A	US 3 978 853 A (MORRISON ROBERT D) 7 September 1976 (1976-09-07)	
A	EP 0 879 661 A (SOFEDIT) 25 November 1998 (1998-11-25)	



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Patent family members are listed in annex.

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Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 00/14779

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4633867	A	06-01-1987	NONE	
EP 0873437	A	28-10-1998	WO 9724477 A CN 1202938 A	10-07-1997 23-12-1998
US 4869267	A	26-09-1989	AU 3694889 A EP 0415996 A WO 8910731 A US 5088478 A US RE34661 E	29-11-1989 13-03-1991 16-11-1989 18-02-1992 12-07-1994
US 3978853	A	07-09-1976	NONE	
EP 0879661	A	25-11-1998	FR 2763523 A	27-11-1998